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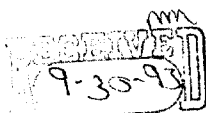
Dear Sir or Madam:

Union Carbide Corporation ("Union Carbide") herewith submits the following information concerning an epidemiology study at Union Carbide's Bound Brook, NJ plant which the Agency may regard as being subject to TSCA § 8(e) reporting under its current guidelines. A nested case-control study was conducted to investigate whether an excess of pancreatic cancer, identified in a cohort mortality study, was associated with potential workplace exposures. The attached draft report (identified below) concludes that: "[o]ver the study period, significant exposure-related process changes occurred... Although PVC [polyvinyl chloride] and PE [polyethylene] processing operations could not be analyzed separately, the pancreatic cancer excess is more likely to be related to PVC processing, since this operation started earlier and involved more numerous potentially hazardous raw materials and exposures. Identification of a causative agent or combination of agents would require investigations with more detailed exposure information".

"Pancreatic Cancer Among Workers Processing Synthetic Resins", S.L. Selenskas, M. J. Teta, J. N. Vitale, Draft Business Confidential Report, Union Carbide Corp., July 23, 1993.

While no assertion of confidentiality is made, the Agency is advised that the publication rights to this information are the property of Union Carbide.

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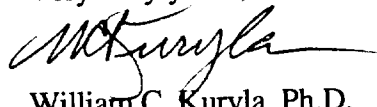


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Please contact the undersigned with questions, if any, at 203/794-5230.

Very truly yours,



William C. Kuryla, Ph.D.
Associate Director
Product Safety

WCK/cr
Attachment

**PANCREATIC CANCER AMONG
WORKERS PROCESSING SYNTHETIC RESINS**

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ABSTRACT

A nested case-control study was conducted to investigate whether an excess of pancreatic cancer, identified in a cohort mortality study, was associated with potential workplace exposures at a chemicals and plastics plant that was founded in the early 1900's. The study population included 28 male pancreatic cancer cases and 140 randomly selected controls, matched on year of birth and at risk (alive) at the time of the case death. Using plant work history records, department and job assignments for the two groups were compared. Workers assigned to a work area which processed PVC and polyethylene (PE) were shown to be at increased risk. Men assigned more than 16 years to this department had a significantly increased risk ratio of 7.15 (95% Confidence Limits (CL) =1.28-40.1). No excess was seen with shorter duration assignments. Seven of the 9 cases began working in this area in the 1940's. Average latency was 32 years and all but 3 cases worked 20 years or more in this unit. Over the study period, significant exposure-related process changes occurred in addition to the use of numerous chemical additives. Although PVC and PE processing operations could not be analyzed separately, the pancreatic cancer excess is more likely to be related to PVC processing, since this operation started earlier and involved more numerous potentially hazardous raw materials and exposures. Identification of a causative agent or combination of agents would require investigations with more detailed exposure information.

INTRODUCTION

The mortality experience of workers at a plastics manufacturing and research and development plant in New Jersey has been examined in several studies as described by Dell and Teta. (1). Impetus for these studies stemmed from the apparent excess of pancreatic cancer noted by the plant physician and from the findings of an inter-industry study of polyvinyl chloride (PVC) fabricators (2). The results of a cohort study, which evaluated workers at this plant between 1946 and 1967, who were followed for mortality through 1983, included an excess of pancreatic cancer among hourly workers which was statistically significant for those employed 10 years or more (SMR=188; 95% CI=108-306) (3). Based on these findings, a nested case-control study was conducted to evaluate whether the excess of pancreatic cancer was related to workplace exposures at the plant. An update of the cohort study through 1988 was also conducted and is reported elsewhere (1).

The epidemiologic literature related to pancreatic cancer and the workplace is expanding, but the results are often exploratory in nature since most of these studies were not intended as detailed investigations of specific exposures. There have been suggestive findings of elevated rates of pancreatic cancer in certain occupational cohorts including petrochemical workers (4,5), chemists (6-8), rubber workers (9,10), and dry cleaners (11).

A few occupational studies have reported an association between pancreatic cancer and a specific exposure, but the excesses have been small or not replicated. Asbestos appeared to be associated with pancreatic cancer among insulation workers;

however, confirmation of death certificate information revealed that a large number of deaths was due to peritoneal mesothelioma, a known asbestos-related disease (12). Other excesses have been reported in association with exposure to methylene chloride (13,14), dichloro diphenol trichloroethane (DDT) (15) and ethylene chlorohydrin production (16).

Blacks experience rates of pancreatic cancer that are approximately 1.5-2.0 times greater than the rates for whites (17). Cigarette smoking has also been consistently identified as a major risk factor for pancreatic cancer in a number of studies (18-20). Evidence has also been accumulating for alcohol consumption (21).

In 1910, Dr. Leo Baekeland formed the Bakelite Company for the production of phenolics and other resins. Until 1931, all production of thermosetting plastics was conducted in Perth Amboy, or Bloomfield, New Jersey. Commercial processes for phenol-formaldehyde resins began at Bound Brook, New Jersey in 1931 (Table 1). A number of other synthetic resin processes which were initiated included vinyl (PVC) processing in 1941, polyethylene (PE) processing in 1947, and phenoxy resins development in 1962.

METHODS

Study subjects for this nested case-control study were selected from a cohort who had worked 7 months or more at the Bound Brook plant between 1946 and 1967. Cases were defined as men who died with pancreatic cancer and had at least one hourly job assignment during that time period. A total of 28 pancreatic cancer deaths meeting these criteria were identified from the cohort mortality study subjects. Dell and Teta (1) reported 25 pancreatic cancer deaths which occurred among the hourly population between 1946 and 1988. Two additional deaths among members of the cohort which occurred after 1988 were identified from company records and another case was found by NIOSH in a review of hospital medical records. According to the hospital records, this individual died with pancreatic cancer but his death certificate erroneously stated cancer of the bile duct.

Using incidence density sampling, five controls per case (n=140) were randomly selected from members of the cohort study with the same year of birth and who had survived in age at least as long as the cases (22).

Prior to the initiation of the present study, it was requested that the National Institute for Occupational Safety and Health (NIOSH) attempt to retrieve and review hospital medical records of 100 former Bound Brook workers whose death certificate causes of death were coded as "cancers of the digestive organs and peritoneum". This request was motivated by: 1) the findings of Selikoff et al. in which a number of pancreatic cancer deaths, as reported on death certificates, among asbestos exposed insulation workers were confirmed to be deaths due to peritoneal mesothelioma and 2)

the fact that one Bound Brook plant used asbestos extensively (12). A total of 74 medical records were obtained (19 of the 28 pancreatic cancer cases) with the remainder being either destroyed or otherwise unobtainable. This review was based entirely on written information contained in patient medical records. The NIOSH review concluded that the death certificate reports of pancreatic cancer agreed with the available medical records.

For each study subject, data were collected from plant medical records, work history records, employment application forms, earnings files and the cohort study database. For subjects whose work history records were missing, the two other resources used to collect similar information were the earnings files (included departments, job titles, and year worked, but only for the years 1941 through 1951) and the cohort study database (included departments and month/year worked, but only for the years 1946 through 1967).

Interview data were not collected for this study because spouses of the cases, if alive, would be very old and unlikely to be able to recall work or lifestyle factors of their deceased husbands that occurred as long as 45 years ago. As of 1991, nearly 50% of the cases were born more than 80 years ago. In addition, although control spouses would be similarly interviewed, answers would lack comparability if their husbands were still alive and communicated their past lifestyle or work experiences.

Exposure assessment for this investigation was facilitated by the characterization of the workplace conducted for the first cohort study (follow-up through 1979) (23). Department and job dictionaries with start and end dates were developed, together with linkage to buildings worked. Quantitative exposure measurements were not available and

the chemical dictionary was never completed. The department and job dictionaries were computerized and expanded for the present investigation using hard copy documentation from the original cohort study.

Study subjects were initially classified into major production and nonproduction work areas based on their ever having been assigned to these areas. The major production work process areas included: resin and varnish, vinyl and polyethylene processing, phenol, formaldehyde, hexamethylenetetramine, resin pulverizing, polystyrene, phenoxy resin, and fibers and fabrics. Nonproduction work areas were engineering, maintenance, offices, distribution, plant service, and research and development. Case and control differences were analyzed within these broad areas for those major work process areas with five or more exposed cases. Subgroups of these major work process areas were then examined similarly. If excess risks were identified, job assignment analyses were conducted.

Conditional logistic regression models for a 1-M matched study were used for the estimation of risk ratios and 95% confidence limits (CL) (24,25). Trends by duration of exposure and time since first exposure (latency) were assessed in separate models, due to the limited number of study subjects. For all analyses, control exposures which occurred after the failure time of the matched case were ignored. Induction time was also taken into account by ignoring case and matched controls' exposures within 10 years prior to the pancreatic cancer death of the case (26). Independent variables were categorized based on quartile cutpoints for all study subjects combined. Variables were dichotomized when the model failed to converge.

Because medical records, which may or may not contain smoking information, were found for only 41% of the study population, cigarette smoking data could not be successfully entered into the model. This also applied to all other information from the medical records which were univariately examined.

RESULTS

Complete payroll records, which included departments, job titles and dates worked, were obtained for 104 of the 168 study subjects (61.9%) [19 cases (67.9%); 85 controls (60.7%)]. Using all sources of information on job and department assignments, complete work history information was available for all but 20 of the subjects (11.9%) [2 cases (7.14%); 18 controls (12.9%)] whose data included some unknown departments and dates worked.

Medical records were found for only 69 subjects (41.1%) [12 cases (42.9%); 57 controls (40.7%)] . Based on the available medical records with smoking information, it was determined that 7 out of the 7 cases (100%) with available information ever smoked cigarettes compared to 18 out of 26 controls (69.2%). For those with alcohol consumption information, 5 out of 7 cases (71.4%) indicated that they consumed alcohol versus 11 out of 24 controls (45.8%) . Although such information is limited, it appears that cases were more likely to smoke cigarettes and consume alcohol.

Cases and controls were hired on average during the same time period, 1944-45. Average duration of employment (approximately 20 years), height (5' 8") and year of birth (1911) were also similar (Table 2). However, cases died approximately 12 years earlier in age than the controls (63.4 versus 75.6). Although the difference was not statistically significant, the cases weighed an average of six pounds less than the controls at time of hire (163 versus 169).

Major production work areas to which at least five cases had been assigned were evaluated for risk by duration of assignment and time since first assignment (Table 3).

There were 9 cases and 40 controls who were ever assigned to the Vinyl and Polyethylene major work area. Although no trend with increasing duration was apparent, there was a seven-fold statistically significant increase in risk ($RR=7.15$, 95% $CL=1.28-40.1$) for those who worked more than 16 years in Vinyl (PVC) and Polyethylene Processing ($n = 5$ cases). A trend was also not seen with time since first assignment in this major production work area. However, risk was elevated for all groups with greater than 26 years since first assignment. No associations or trends were observed for duration or time since first assignment for either the Resin Pulverizing or Resins and Varnish major work areas.

Only two major nonproduction work areas had five or more exposed cases, Plant Service and Maintenance. A nonsignificant increased risk ratio of 3.49 (95% $CL=0.73-16.7$) was reported for those workers assigned to Maintenance for 2.5 to 6.5 years (Table 4). The risk ratios for longer duration assignments were not elevated. A nonsignificant increase in risk ($RR=1.78$, 95% $CL=0.57-5.57$) was also seen for over 27.5 years since first assignment to this major work area.

Specific subdepartments within the Vinyl and Polyethylene Processing major work area were examined due to the significant finding in the highest category of duration (Table 5). A total of 8 out of the 9 cases and 34 out of the 40 controls worked specifically in the Vinyl and Polyethylene Processing subdepartment. The group with more than 18 years duration (4 cases; 6 controls) had an almost nine-fold excess of pancreatic cancer ($RR=8.98$, 95% $CL=0.90-89.8$) (Table 6). There was no clear trend with time since first assignment. The highest levels of risk were seen in the longest

latency periods, 35.5 to 38.5 years (RR=2.10, 95% CL=0.43-10.2) and greater than 38.5 years (RR=1.52, 95% CL=0.24-9.50).

Characteristics of the 8 cases who worked in this department are shown in Figure 1. Nearly all cases were first assigned to this department in the 1940's. The last case to leave this department was in 1975. Average latency was 32.1 years and, ignoring the ten year induction period, 6 of the cases worked approximately 20 years or more in this department. Age at death ranged from 48 to 81 years, with a mean of 63 years.

Patterns of job assignments for cases and controls assigned for more than one year to the Vinyl and Polyethylene Processing Department are presented in Table 7. For the six job titles to which two or more cases were assigned more than one year, there were no statistically significant differences for either job assignment or duration. Cases did not appear to cluster by job assignment, although they were somewhat more likely to work as Banbury Operators compared to controls (38% versus 18%) and were assigned for a longer average duration to that position (5.1 versus 2.4 years). These 3 cases worked at least 22 years in this department and had other various job assignments.

DISCUSSION

This investigation utilized existing records to evaluate whether pancreatic cancer risk was associated with workplace exposures at a chemicals and plastics plant that was founded in the early 1900's. Work histories were complete for nearly all subjects but plant medical records were found for less than half the study group.

Due to sparse medical data, cigarette smoking and alcohol consumption information could not be assessed as potential confounders. However, in a nested case-control study of pancreatic cancer among chemical manufacturing workers, Garabrant et al. reported that controlling for smoking and other potential confounders did not considerably alter the risks associated with chemical exposures (15). In addition, it is unlikely that cigarette smoking or alcohol consumption patterns of hourly workers, similar in age, would vary by job assignment and bias the risk estimates in this study.

Information on race was obtained for this investigation for all 28 cases from death certificates and for only 95 controls (67.9%) from applications for hire or medical records. Three of the cases (10.7%) and 2 of the controls (2.1%) were black. The race data for controls was also too incomplete to formally incorporate into the analysis. The positive association with long term assignment to vinyl and polyethylene processing is unlikely, however, to be explained by failure to control for race, since none of the three black cases ever worked in this unit.

Although both PVC and polyethylene processing use the same equipment and analogous processes, there were important exposure-related differences between the two. In operation at this site since 1941, vinyl processing involved compounding and

calendering PVC polymers and copolymers produced at other locations. PE processing, also using polyethylene produced at other locations, began in 1947 and expanded by the mid-1950's to become as important as the vinyls operation. Both operations were contained in the same building and identified by the same department codes until the vinyl operations ceased in 1976. This same department also included other workers in another building processing PE only.

At its peak, vinyl processing involved approximately 90 different job titles and ran operations continuously using four shifts. Bulk PVC resin was pre-blended with plasticizers (to increase material flexibility and workability), stabilizers (to maintain physical and chemical properties of the compounded materials), solvents (for surface coatings), waxes (to aid processing) and dyes (to add color). Prior to the 1950's, these materials were weighed fed manually into a blender. Workers climbed inside the blenders to scrape off excess chemical residues, whenever different additives were required for a somewhat different final product. This occurred frequently, as often as twice a day. The semi-dry products were then transported on a conveyor to a Banbury, a mixer that maintains an elevated temperature for the compounding of plastics. The resin compound was then calendered into a sheet of dough-like consistency forming thermoplastic sheeting or film by passing the material through a series of heated rollers.

PE processing involved blending weighed amounts of polyethylene resin, carbon black, peroxides (dicumyl peroxide, varox peroxide), along with antioxidants which acted as fillers and stabilizers. These were then also transported on a conveyor to a Banbury for further homogenization. Because polyethylene is inherently flexible,

formulation with plasticizers was not necessary. The blenders used in PE processing were not cleaned very often because there was little variation in the additives used. The plastic material emerged from the die-plate, molten in spaghetti-like form, was cooled and then pelletized. The pellets were dried and packaged.

The processing of both vinyl and polyethylene was conducted under strict conditions to prevent cross contamination. Production bays were partitioned in order to prevent the products of one process from contaminating that of another. The machinery which was used for vinyl and polyethylene processing was never interchanged. Workers were also required to wear goggles, gloves, and filter breathers to prevent exposure to harmful toxins. Through promotions, long-term workers were eventually assigned to both polyethylene and vinyl processing as they were given the responsibility of managing more bay areas. Automation between the 1950's and 1960's introduced mixers which made the pre-blending and Banbury processes obsolete.

A number of studies have shown that the principal hazards of plastics are associated with their monomers and with the wide variety of additives that are used in processing them (33-35). The evidence for carcinogenicity of PVC and PE from both human and animal studies is considered inadequate by the International Agency for Research on Cancer (IARC) (36).

Various studies have investigated the effects of exposure, mostly in association with angiosarcoma of the liver in PVC production, in which PVC resins are manufactured from vinyl chloride monomer (27-29). Of those investigations, none reported an excess of pancreatic cancer. Fewer studies have evaluated the effects of

exposure within the processing of semi-finished plastic products which involve a number of other raw materials but minimal exposure potential to vinyl chloride. Although the excesses were weak, four studies have shown elevated risks associated with PVC processing and digestive system tumors (2, 30-32). Only one of these investigations included follow-up beyond 1976 (35). This cohort study was conducted among 2,031 male workers in a PVC processing plant who worked between 1945-1980 and were followed through 1985. Risk was slightly elevated for digestive system tumors. The more striking findings in the present investigation may be a result of longer follow-up, more workers with extended durations of assignments, and a larger number of pancreatic cancers, a rare disease. Average latency for the cases assigned to Vinyl and Polyethylene Processing was over 30 years.

Plasticizers are considered an important category of additives based on the potential toxicity of chemicals in this category and their large-scale use in processing PVC resins. Approximately fifty percent of the additives used in processing PVC resins are plasticizers (37). Phthalate and adipate plasticizers were used in vinyl processing at Bound Brook, specifically di(2-ethyl hexyl) phthalate (DEHP), the most commonly used plasticizer in PVC processing as well as the most studied. It has been reported that DEHP increases the incidence of hepatocellular carcinomas in both mice and rats (38), although there is no evidence of adverse health effects in humans.

Stabilizer content as an additive in PVC processing can amount to up to 10%. Specific compounds listed in the chemical dictionary included: dibutyltin dilaurate, calcium stearate, lead stearate, cadmium stearate, lead sulfate, lead phosphite, lead

phthalate, lead silica sulfate, lead distearate and barium-cadmium. Barium-cadmium stabilizers are the most widely used in PVC processing. IARC has evaluated and found sufficient evidence of carcinogenicity in experimental animals for cadmium and cadmium compounds (respiratory and prostate tumors) and lead and lead compounds (renal tumors) (36). The results of one experimental study suggested an increased incidence of pancreatic islet cell tumors by administration of cadmium chloride via the injection route (39). Used on a much smaller scale, other additives included solvents, lubricants, waxes, fillers, and dyes. Specific solvents used in vinyl processing included methyl ethyl ketone, toluene, and acetone which are not known to be carcinogens.

Fibers and fabrics was another major production work area which involved different work processes yet used similar additives (including DEHP and barium-cadmium stabilizers) as vinyl processing. This was a smaller operation which began in 1965 and existed for only 11 years. One case and two controls were found to have worked in this major work area.

Interviews with retirees with long-term assignment to the vinyl and polyethylene processing work area confirmed that all the cases assigned to this department were in the building where both PVC and PE were processed and none were assigned to the building processing PE only. Since the conclusion of this case-control study, another pancreatic cancer death has emerged from the cohort study population. This decedent was also assigned to Vinyl and Polyethylene Processing (29 years).

The absence of historical industrial hygiene data for the numerous chemicals involved makes it impossible to reconstruct specific exposures to individuals. However,

this investigation provides convincing evidence that pancreatic cancer risk is associated with long-term assignment in the early years of operation to the Vinyl and Polyethylene Processing work area. It is likely that pancreatic cancer is associated with prolonged exposure to the products of PVC processing, since this operation started earlier and involved more numerous potentially hazardous raw materials and exposures due to the routine manual cleaning of blenders. Nearly all of the pancreatic cancer cases were assigned to this work area before PE processing was initiated in 1947 and none worked in the building processing PE and not PVC. In addition, prior studies suggest a consistent pattern of excess risk for digestive system cancers and PVC processing. Updates of those cohorts which include PVC but no PE processing could confirm this conclusion. Identification of a causative agent or combination of agents, however, would require investigations of workers in similar workplace environments with more detailed exposure information.

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Table 1

Major Production Work Areas, Years of Operation,
and Associated Major Chemicals

<u>Major Production Work Area</u>	<u>Years of Operation</u>	<u>Major Chemicals</u>
• Phenol Production	1931 - 1980	<ul style="list-style-type: none"> • phenol • acetophenone • acetone • alpha-methyl styrene • cumene
• Formaldehyde Production	1931 - 1976	<ul style="list-style-type: none"> • methanol • formaldehyde
• Resins and Varnish Processing	1931 - 1976	<ul style="list-style-type: none"> • alkylated phenols • formaldehyde • creosols • cresylic acid • alkylomanines or mono di-aryl • bisphenol A • epichlorohydrin • isobutylene • hexamethylenetetramine • acrylic resins • linseed oil • common solvents • barium and lead salts • chrome sludge • organic acids • carbon black • nigrosene
• Hexamethylenetetramine	1932 - 1976	<ul style="list-style-type: none"> • formaldehyde • ammonia • hexamethylenetetramine

Table 1 (continued)

Major Production Work Areas, Years of Operation,
and Associated Major Chemicals

<u>Major Production Work Area</u>	<u>Years of Operation</u>	<u>Major Chemicals</u>
• Resin Pulverizing	1935 - 1975	<ul style="list-style-type: none"> • phenolic resins • wood flour • asbestos • coal dust • other fillers • hexamethylenetetramine • urea • resorcinol • pigments and dyes
• Polystyrene	1937 - 1976	<ul style="list-style-type: none"> • styrene • vinyl benzene • toluene • methyl ethyl ketone • triethylchloride • triethylchlorine • polystyrene
• Vinyl Processing and Polyethylene Processing	1941 - 1976 1947 - Present	<ul style="list-style-type: none"> • polyvinyl chloride resin • phthalates plasticizers • adipate plasticizers • tin • dyes and pigments • lead • waxes • asbestos • barium-cadmium stabilizers • polyethylene resins • solvents • dicumyl peroxide • carbon black

Table 1 (continued)

Major Production Work Areas, Years of Operation,
and Associated Major Chemicals

<u>Major Production Work Area</u>	<u>Years of Operation</u>	<u>Major Chemicals</u>
<ul style="list-style-type: none">• Phenoxy Resins	1962 - 1965	<ul style="list-style-type: none">• bisphenol A• epichlorohydrin• toluene• butanol• caustic mix
<ul style="list-style-type: none">• Fibers and Fabrics	1965 - 1976	<ul style="list-style-type: none">• polyvinyl chloride• pigments/dyes• azeolate• phthalates• phosphate plasticizers• stearates of lead• zinc or calcium• azodicarbonamide• acrylic copolymers• stabilizers (barium and cadmium)• ketone solvents

Table 2

Characteristics of Study Population

	Cases (n = 28)		Controls (n = 140)	
	Mean	Std. Dev.	Mean	Std. Dev.
Birth Year	1911	12.7	1911	12.7
Hire Year	1945	5.46	1944	6.23
Duration of Employment (years)	20.7	14.0	20.2	14.4
Age at Death	63.4	9.04	75.6 ¹	8.86
Height ² (inches)	68.6	2.32	68.1	3.20
Weight ² (pounds)	163	13.5	169	23.4

¹ For deceased (n = 67) controls.

² At hire, complete for 19 (68%) cases and 85 (61%) controls on application forms.

Table 3

**Risk Ratios and 95% Confidence Limits (CL) for Major Production Work Areas
With Five or More Cases¹**

Duration			Time Since First Assignment		
Number of Years	Risk Ratio	95% CL	Number of Years	Risk Ratio	95% CL
<u>Vinyl and Polyethylene Processing</u> (9 Cases; 40 Controls) ²					
≤ 1	0.54	(0.06-4.57)	≤ 26	1.00	(0.20-5.00)
1*-5	0.84	(0.16-4.30)	26*-36	1.12	(0.22-5.78)
5*-16	0.47	(0.06-3.84)	36*-39.5	1.56	(0.34-7.24)
>16	7.15*	(1.28-40.1)	>39.5	1.25	(0.20-7.87)
<u>Resin Pulverizing</u> (10 Cases; 55 Controls)					
≤ 1	1.34	(0.39-4.54)	≤ 23	1.02	(0.25-4.23)
1*-1.5	0.86	(0.09-8.06)	23*-29	0.66	(0.13-3.43)
1.5*-5.5	0.41	(0.09-1.97)	29*-39	0.93	(0.23-3.73)
>5.5	0.99	(0.26-3.76)	>39	0.78	(0.14-4.23)
<u>Resins and Varnish</u> (5 Cases; 32 Controls)					
≤ 0.5	0.90	(0.10-7.84)	≤ 25	1.21	(0.22-6.52)
0.5*-2.5	0.86	(0.19-4.02)	25*-28.5	0.60	(0.07-4.83)
2.5*-10.5	0.67	(0.08-5.54)	28.5*-38	0.60	(0.07-4.86)
> 10.5	0.54	(0.07-4.28)	> 38	0.58	(0.07-4.93)

¹ Exposures with 10 years of case death excluded.² Number of exposed cases and controls in parentheses

* Categories do not include lower bounds.

* p< 0.05

Table 4

Risk Ratios and 95% Confidence Limits (CL) for Major
NonProduction Work Areas with Five or More Cases¹

Duration			Time Since First Assignment		
Number of Years	Risk Ratio	95% CL	Number of Years	Risk Ratio	95% CL
<u>Plant Service</u> (8 Cases; 38 Controls) ²					
≤ 2.5	1.50	(0.50-4.51)	≤ 29.5	0.75	(0.20-2.86)
> 2.5	0.70	(0.18-2.74)	> 29.5	1.43	(0.47-4.41)
<u>Maintenance</u> (10 Cases; 42 Controls)					
≤ 2.5	0.92	(0.18-4.72)	≤ 27.5	0.98	(0.30-3.26)
2.5*-6.5	3.49	(0.73-16.7)	> 27.5	1.78	(0.57-5.57)
6.5*-16.5	1.07	(0.21-5.36)			
>16.5	1.00	(0.20-4.91)			

¹Exposures with 10 years of case death excluded.

² Number of exposed cases and controls in parentheses.

* Categories do not include lower bounds.

Table 5

Subgroup Departments of the Major Production Work
Area of Vinyl and Polyethylene Processing

- **Vinyl and Polyethylene Processing**
- Production Engineering
- Work Laboratory/Works Lab Vinyl, Polyethylene
- Vinylite Works Control/Quality Control - Vinyl, Polyethylene and Flourothene
- Shipping
- Works Lab and Inspection T/P Production
- Works Lab Phenolics and Styrene
- Oiled Carbon Black
- Product Records
- Vinyl Rigid
- Vinyl Rigid Planished
- Rigid Vinyl Liquid Molding Compounds
- Vinyl Granular
- Cast Film
- Vinyl Fabrication
- Vinyl Flexible, Calendered
- Quality Control Polyethylene
- Polyethylene Fabrication

Table 6

Risk Ratios and 95% Confidence Limits (CL) for Vinyl and
Polyethylene Processing Subdepartment, 1941 - Present¹

Duration			Time Since First Assignment		
<u>Number of Years</u>	<u>Risk Ratio</u>	<u>95% CL</u>	<u>Number of Years</u>	<u>Risk Ratio</u>	<u>95% CL</u>
<u>1941-Present:</u> (8 Cases; 34 Controls) ²					
≤1	0.68	(0.08 - 5.82)	≤25.5	1.48	(0.26 - 8.38)
1*-5	0.55	(0.07 - 4.47)	25.5*-35.5	0.51	(0.06 - 4.13)
5*-18	1.19	(0.25 - 5.61)	35.5*-38.5	2.10	(0.43 - 10.2)
>18	8.98	(0.90 - 89.8)	>38.5	1.52	(0.24 - 9.50)

¹Exposures with 10 years of case death excluded.

²Number of exposed cases and controls in parentheses.

*Categories do not include lower bounds.

*p<0.05

Table 7

Job Assignment Comparisons¹ of Pancreatic Cancer Cases and Controls
Employed in the Vinyl and Polyethylene Processing Department.

Job Title	Cases (n=8)		Average Duration (y)	Controls (n=34)		Average Duration (y)
	n	(%)		n	(%)	
Chief Operator, Polyethylene Compounding and Blending	2	(25.0)	13.2	4	(11.8)	7.8
Chief/Utility Operator, Weigh and Blend	2	(25.0)	6.7	1	(2.9)	6.3
Granular Bulk Loader and Packer	2	(25.0)	2.0	1	(2.9)	5.0
Composite Weigher	2	(25.0)	2.5	0	(0)	-
Take Off Operator and Packer: Calendered Products and Granular Materials	3	(37.5)	2.9	6	(17.7)	2.4
Banbury Operator (All types)	3	(37.5)	5.1	6	(17.7)	2.4

¹ Unmatched comparison for jobs to which 2 or more cases were assigned more than one year.

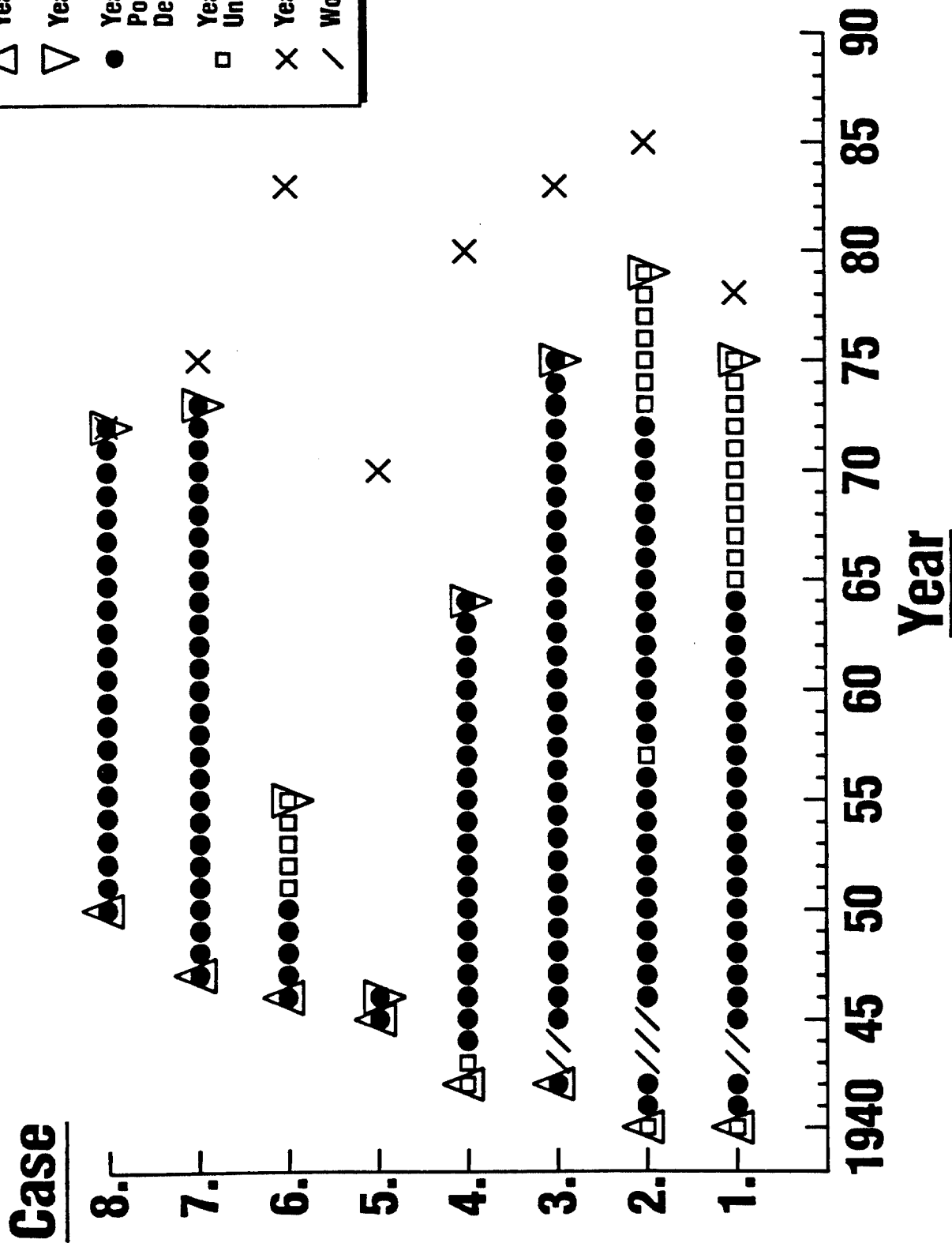
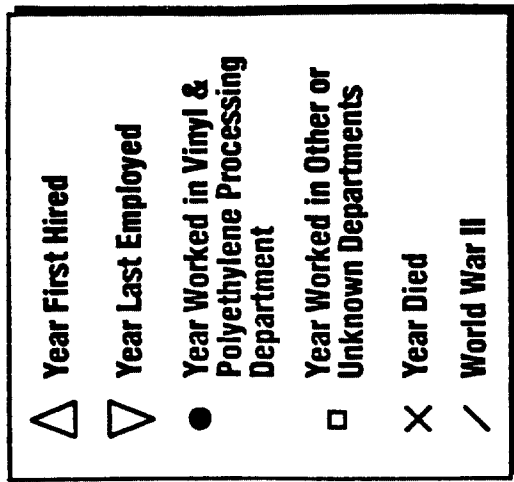


Figure 1

Work Histories of the Eight Pancreatic Cancer Cases Who Worked in
Vinyl and Polyethylene Processing Department.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

William C. Kuryla, Ph.D.
Associate Director, Product Safety
Union Carbide Corporation
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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

JAN 25 1994

This letter formally acknowledges EPA's receipt of information submitted by your organization under Section 8(e), the "substantial risk" information reporting provision of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA Section 8(e) Document Control Number (i.e., 8EHQ-0000-0000 Init.) assigned by EPA to your submission(s). Please refer to this cited number when submitting follow-up or supplemental information.

Please note that all submitted correspondence will be placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA Section 8(e) policy statement (43 FR 11110, March 16, 1978).

Confidential submissions submitted pursuant to the TSCA Section 8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims, because substantiation of CBI claims is required at the same time the 8(e) CAP is submitted to EPA. (If not done so already, please ensure that this information is provided to the Agency). When substantiating any/all claims, answer the questions detailed in the following attachment.

For NON-CAP submissions, any confidentiality claims should be supported by submission of information as described in the attachment(s).

12188 A



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TEST DATA: 0893-12188 SEQ A

TYPE (INT) SUP FLWP

INITIATOR NAME: Union Carbide Corporation

INFORMATION REQUESTED: FLWP DATE
0901 NO INFO REQUESTED
0902 INFO REQUESTED (TECH)
0903 INFO REQUESTED (VOL ACTIONS)
0904 INFO REQUESTED (REPORTING RATIONALE)
DISPOSITION:
0905 REFER TO CHEMICAL SCREENING
0906 CAP NOTICE

U.S. DATE: 08/12/93 OTS DATE: 08/17/93 CRAD DATE: 09/30/93

CHEMICAL NAME:

Poly Vinyl Chloride
Polyethylene

CASE#
9002-86-2
9002-88-4

INFORMATION TYPE:

L F C

INFORMATION TYPE:

L F C

INFORMATION TYPE:

L F C

201 ONCO (HUMAN) 01 02 04
202 ONCO (ANIMAL) 01 02 04
203 CELL TRANS (IN VITRO) 01 02 04
204 MUTA (IN VITRO) 01 02 04
205 MUTA (IN VIVO) 01 02 04
206 REPROTERATO (HUMAN) 01 02 04
207 REPROTERATO (ANIMAL) 01 02 04
208 NEURO (HUMAN) 01 02 04
209 NEURO (ANIMAL) 01 02 04
210 ACUTE TOX (HUMAN) 01 02 04
211 CHR. TOX (HUMAN) 01 02 04
212 ACUTE TOX (ANIMAL) 01 02 04
213 SUB ACUTE TOX (ANIMAL) 01 02 04
214 SUB CHRONIC TOX (ANIMAL) 01 02 04
215 CHRONIC TOX (ANIMAL) 01 02 04

2016 EPIC IN 01 02 04
2017 HUBC N EXPOS (PROD CONTAM) 01 02 04
2018 HUBC N EXPOS (ACCIDENTAL) 01 02 04
2019 HUMAN EXPOS (MONITORING) 01 02 04
2020 ECO/NOVA TOX 01 02 04
2021 ENV. OCCURRENCE/FATE 01 02 04
2022 BMRB INCI OF ENV CONTAM 01 02 04
2023 RESPONSE REQUEST DELAY 01 02 04
2024 PRODCON/CHRM ID 01 02 04
2025 REPORTING RATIONALE 01 02 04
2026 CONFIDENTIAL 01 02 04
2027 ALLERG (HUMAN) 01 02 04
2028 ALLERG (ANIMAL) 01 02 04
2029 METAB/PHARMAC (ANIMAL) 01 02 04
2030 METAB/PHARMAC (HUMAN) 01 02 04

0241 BMRBNO (ANIMAL) 01 02 04
0242 BMRBNO (HUMAN) 01 02 04
0243 CHEM/PHYS PROP 01 02 04
0244 CLASTO (IN VITRO) 01 02 04
0245 CLASTO (ANIMAL) 01 02 04
0246 CLASTO (HUMAN) 01 02 04
0247 DNA DAMAGE/REPAIR 01 02 04
0248 PRODCUSE/PROC 01 02 04
0249 NEEDS 01 02 04
0250 OTHER 01 02 04

IMAGE DATA: NON-ORL INVENTORY

ONGOING REVIEW

SPECIES

TOXICOLOGICAL CONCERN:

USE:

PROPOSED DATE:

YES (CONTINU.)
NO (DROP)
DETERMINE
REFER:

LOW
MED
HIGH

COMPOSITE Non-CAP

VOLUNTARY ACTIONS:
0901 NO ACTION REPORTED
0902 STUDIES PLANNED/UNDERWAY
0903 NOTIFICATION OF WORK: R01111 H
0904 LABEL/MSDS CHANGES
0905 PROCESS/HANDLING CHANGES
0906 APPAUSE DISCONT. NEEDED
0907 PRODUCTION DISCONTINUED
0908 CONFIDENTIAL